



## Fast Track Proposed Regulation Agency Background Document

<b>Agency name</b>	Department of Health
<b>Virginia Administrative Code (VAC) citation</b>	12 VAC 5-481
<b>Regulation title</b>	Radiation Protection Regulations
<b>Action title</b>	Amend regulation to adopt federal order requiring fingerprinting of individuals having access to certain radioactive materials.
<b>Date this document prepared</b>	March 21, 2008

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

*Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.*

The Virginia Department of Health (VDH) intends to amend the existing Radiation Protection Regulations (12VAC5-481) to adopt an order issued on December 5, 2007 by the U.S. Nuclear Regulatory Commission to its radioactive materials licensees. The order requires radioactive material licensees that have certain quantities of radioactive materials of concern to have individuals who have unrestricted access to these materials fingerprinted and their names compared with those on the national terrorist screening database.

The VDH anticipates entering into an agreement with the NRC for assuming regulatory authority of NRC's licensees located in Virginia during 2009. VDH is required to implement federal regulations and orders applicable to this regulatory activity. These proposed regulations are intended to supersede the Radiation Protection Regulations, which became effective August 21, 2006.

### Statement of final agency action

*Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.*

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On April 18, 2008, The State Board of Health voted to amend the proposed regulation 12VAC5-481 (Radiation Protection Regulations).

### Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.*

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These regulations are authorized by the Code of Virginia Sections 321.-229 et seq. Section 32.1-229 authorizes the Board of Health to: 1) Establish a program of effective regulation of sources of radiation for the protection of the public health and safety; 2) Establish a program to promote the orderly regulation of radiation within the Commonwealth, among the states and between the federal government and the Commonwealth and to facilitate intergovernmental cooperation with respect to use and regulation of sources of radiation to the end that duplication of regulation may be minimized; and 3) Establish a program to permit maximum utilization of sources of radiation consistent with the public health and safety.

Refer to the following web site for viewing the statutory authority cited in Section 32.1-229 of the Code of Virginia: <http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-229>

The Office of the Attorney General issued a statement that the proposed Radiation Protection Regulations had been reviewed and that the Department possesses the authority to promulgate these regulations pursuant to Chapter 6, Article 8 of Title 32.1 of the Code of Virginia.

### Purpose

*Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.*

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The NRC requires Agreement States, i.e. those states that have an agreement with the NRC for the regulation of radioactive materials, to adopt and implement NRC regulations and orders. The Governor has informed the NRC of the Commonwealth's intention to submit an application for such an agreement. Recently the NRC informed VDH staff that an Order NRC issued on December 5, 2007 will need to be addressed in the application that VDH intends to submit in the spring of 2008. The Commonwealth will need to implement the Order on the date of signing the agreement, tentatively set for July 2009.

The NRC chose to issue an Order rather than use the regulatory process given the concern for security of the homeland and the urgency expressed by Congress and the public that potential terrorists are denied access to radioactive materials for terrorist activities. The goal of this regulatory action by VDH is to ensure continuity of regulatory requirements during the transition of regulatory authority from the NRC to VDH. Furthermore, by incorporating in VDH regulations the NRC Order that requires certain radioactive materials licensees to fingerprint those individuals who have unrestricted access to certain radioactive materials will reduce the paperwork required of these licensees compared to the alternatives, which

would be for VDH to implement this requirement by issuing its own Order, or if VDH were to include the new requirements in license specifications. Currently NRC licensees must keep a copy of the Order or licensing condition in a separate location from the source and are accountable for keeping a copy in their possession. Many of the Agreement States are using the regulatory process to relieve their licensees from this regulatory burden.

### Rationale for using fast track process

*Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?*

To ensure continuity of regulatory activity, the NRC will require VDH to implement the December 5, 2007 NRC Order on the date of signing the state agreement with the NRC for the transfer of authority for regulating radioactive materials, tentatively set for July 2009. This deadline cannot be met through the normal regulatory process that requires about two years to complete the adoption of a regulation. The fast track approach will reduce implementation to less than a year and allow the regulation to be in place on the date transfer of authority is projected to take place.

The regulation should be noncontroversial, since the affected NRC licensees must comply with the NRC Order prior to June 2, 2008, even in the absence of a VDH regulation. The adoption of the proposed regulation will also provide some relief from a paperwork requirement once the agreement is signed in the year 2009.

*Please note: If an objection to the use of the fast-track process is received within the 60-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objection with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.*

If there is an objection to the fast-track process, VDH will pursue the alternative of seeking to issue an order similar to NRC's, effective on the date of signing the agreement with the NRC for the transfer of authority for regulating radioactive materials.

### Substance

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.)*

New provisions require certain radioactive material licensees to:

- Establish and maintain a fingerprinting program for individuals who require unescorted access to radioactive materials.
- Certify an individual with the responsibility to determine the trustworthiness and reliability of another individual requiring unescorted access to the radioactive materials
- Notify VDH within 24 hours if the results of a FBI identification and criminal history records check indicate that an individual is identified on the FBI's Terrorist Screening Database
- Provide protection of the results of FBI identification and criminal history record checks

- Notify each affected individual that fingerprints will be used to secure a review of his criminal history record
- Provide an individual adversely affected by a records check the procedure for providing corrected or complete information before a decision is rendered.
- Exempt certain employees from the fingerprinting requirement; the new provisions also place prohibitions on the licensee for misuse of the information that would infringe upon the constitutional rights of any individual.

The proposed regulation defines radionuclides of concern by including a list of radioactive materials and threshold quantities for each radioisotope..

**Issues**

*Please identify the issues associated with the proposed regulatory action, including:  
 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;  
 2) the primary advantages and disadvantages to the agency or the Commonwealth; and  
 3) other pertinent matters of interest to the regulated community, government officials, and the public.  
 If there are no disadvantages to the public or the Commonwealth, please indicate.*

1.Primary advantages and disadvantages to the public:

The primary advantage to the public is that the fingerprinting requirement is more visible as a regulation than an order issued to specific radioactive material licensees and thus the public is assured that government is making an effort to prevent terrorists from obtaining radioactive materials for their activities.

There are no disadvantages to the public in promulgating the proposed regulation.

2. Primary advantages and disadvantages to the agency and Commonwealth:

Approving the proposed regulation will address NRC’s requirement that the state’s regulatory program for radioactive materials is compatible and adequate to NRC when the Commonwealth signs an agreement with the NRC for this activity.

There are no disadvantages to the agency and the Commonwealth in promulgating the proposed regulation.

3. The NRC has implemented the requirements in the proposed regulation by an Order issued on December 5, 2007 and requires compliance by June 2, 2008. VDH will need to have these requirements in place on date of agreement with the NRC, tentatively July 2009.

**Requirements more restrictive than federal**

*Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.*

There are no requirements in the proposed regulation that are more restrictive than the applicable federal requirements.

**Localities particularly affected**

*Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.*

None

**Regulatory flexibility analysis**

*Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.*

1. The proposed regulation cannot be less restrictive than the NRC Order.
2. The proposed regulation cannot become effective until the Commonwealth enters into an agreement with the NRC, tentatively July 2009. All licensees will need to comply with this requirement under federal jurisdiction by June 2, 2008.
3. The proposed rule will require VDH licensees to submit finger print cards and personal history directly to the NRC, rather than directly to VDH, which would then forward the records to the NRC. The NRC Order did exempt individuals who may have already completed an FBI criminal history check for other activities.
4. The proposed regulation is required to be identical to the NRC ‘s Order. There is no provision made for specific performance standards for small business licensees.
5. The proposed regulation is required to be identical to the NRC ‘s Order. There is no provision made to exempt small business licensees from these requirements.

**Economic impact**

*Please identify the anticipated economic impact of the proposed regulation.*

<p><b>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</b></p>	<p>The funding for this activity will be supported by licensing fees from the radioactive material users. Fund 0280. The implementation of the fingerprinting requirement will be borne by the NRC until an agreement is signed with the NRC. Thereafter the annual cost to ensure compliance will add less than \$1,000 to the cost of inspections annually.</p>
<p><b>Projected cost of the regulation on localities</b></p>	<p>None</p>

<p><b>Description of the individuals, businesses or other entities likely to be affected by the regulation</b></p>	<p>The affected radioactive materials licensees are those that have large quantities of certain radioactive materials and include medical facilities, engineering and gas drilling firms.</p>
<p><b>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.</b> Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>There are 25 radioactive material licensees in Virginia that are impacted by the NRC Order and whose licenses would transfer to Virginia in an agreement with the NRC. About 12 are small businesses.</p>
<p><b>All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</b></p>	<p>The cost of an FBI criminal history records check and fingerprinting is about \$100 per employee. The costs of reporting, recordkeeping, and other administrative costs are unknown; however, should be less than \$100 annually.</p>

**Alternatives**

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.*

There are two alternatives to implementing the NRC’s Order. First, VDH could issue an order identical to the NRC Order, effective on the date of an agreement with the NRC for the transfer of authority for the regulation of radioactive materials in Virginia. Secondly, VDH could impose the fingerprinting requirements as a licensing condition. In the first case, an order is designed to address an immediate concern. VDH expects the NRC to eventually adopt the fingerprinting requirements as a regulation. The second alternative may appear arbitrary to the regulated community unless there is a regulatory requirement for the license condition. In either case the licensee would need to retain a copy of the order or license condition and make these documents available upon inspection. The adoption of the proposed regulations would provide the licensee relief from this retention requirement.

**Family impact**

*Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

The proposed changes would not have a direct impact on the institution of the family and family stability.

**Detail of changes**

*Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.*

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

For changes to existing regulations, use this chart:

<b>Current section number</b>	<b>Proposed new section number, if applicable</b>	<b>Current requirement</b>	<b>Proposed change and rationale</b>
New Requirement	12VAC5-481-451	No requirement for Fingerprinting	<p>Increased Controls and Fingerprinting- requires certain licensees to designate a Trustworthy and Reliability official responsible for implementing background investigations and fingerprinting employees who are permitted unrestricted access to certain types and quantities of radioactive materials. Requires notification to the NRC whenever an employee's name matches that on the FBI's Terrorist Screening database.</p> <p>Provides prohibitions, protection of information and rights of employees to provide and complete information.</p> <p>Rationale: Adopt federal requirements for controls and fingerprinting individuals who are permitted unrestricted access to certain types and quantities of radioactive materials.</p>

Enter any other statement here